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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,916	10/06/2003	Nader Najafi	IB-10	2944

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EXAMINER	
PATEL, NATASHA	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/679,916	NAJAFI ET AL.	
	Examiner	Art Unit	
	Natasha N. Patel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,23,24 and 29-38* is/are pending in the application.

4a) Of the above claim(s) *22 and 25-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,23,24,29-35 and 37* is/are rejected.

7)☒ Claim(s) *36,38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on 4 August 2006 has been received and considered. By this amendment, Claims 22 and 25-28 have been cancelled, Claims 1-21, 23-24, and 29-38 have been amended, and no new Claims have been added. As a result, Claims 1-21, 23-24, and 29-38 are now pending in the application.

Specification

In view of the Applicant's modification to the Specification with regards to the subject matter of Claims 33, 37, and 38 and typographical/grammatical matters, the Examiner is withdrawing the objection, which was made against the specification in the last Office Action.

Claim Rejections - 35 USC § 112

In view of the Applicant's modification to Claims 19, 20, 23, 32, and 35, the Examiner is withdrawing the rejection of Claim 32 under 35 USC § 112, second paragraph, which was made in the last Office Action.

Claim Rejections - 35 USC § 101

In view of the Applicant's modification to Claims 9, 24, and 30 under 35 USC § 101, the examiner is withdrawing the rejection, which was made in the last Office Action.

Response to Arguments

Applicant's arguments filed on 4 August 2006 have been fully considered but they are not persuasive. Govari's (6,053,873) stent 24 is an implantable cardiac conduit since it is a tube-like structure (see Figure 6) that is capable of being used in the cardiac system (see col. 6, lines 57-62).

Furthermore, Pawlak's valve 10 is an implantable cardiac conduit as well since it is a tube-like structure (see Figure 1) that is used in the cardiac system (see Figure 14) and redirects blood through passageway 16 instead of through the defective valve.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6, 8-21, 23-24, and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Govari et al. (US Patent 6,053,873), hereinafter Govari II.

3. Regarding Claim 1, Govari II discloses a cardiac conduit system comprising: An implantable cardiac conduit (see stent 24) adapted for carrying blood flow to bypass a conduit of a patient heart (see blood vessel 20) when implanted in the patient (see col. 18, lines 44-45). The blood is redirected, or bypassed, through the lumen of the stent so that the blood is no longer flowing through the lumen of the original blood vessel. Furthermore, it has been held that the recitation that an element is "adapted for" a specific function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense (*In re Hutchinson,* 69 USPQ 138). The examiner considers that the stent is *capable* of bypassing the conduit (blood vessel 20) of the patient's heart.

At least one sensing device (see col. 3, lines 28-30) chronically located within said cardiac conduit (stent 24), said sensing device comprising of at least one inductor coil (see coil 94, col. 14, lines 56-63) and at least one means (sensor 84) for monitoring one or more physiological parameters for diagnosis of the condition of said cardiac conduit after said cardiac conduit is implanted in the patient (see col. 2, lines 28-32), with optional electronic components (circuitry 26); and

A non-implantable readout device (see receiver, col. 3, lines 14-18) comprising at least one inductor coil (see col. 4, lines 58-60) allowing electromagnetic telecommunication (see col. 4 line 60 - col.5, line 3) and electromagnetic wireless powering (see col. 3, lines 35-43) of said sensing device through said at least one inductor coil of said sensing device (see col. 3, lines 49-57).

4. Regarding Claim 2, Govari II discloses at least one sensing device comprises of at least one capacitive sensor (see col. 6, lines 31-32).

5. Regarding Claims 3 and 4, Govari II discloses at least one sensing device comprises a battery (see col. 13, lines 22-23), wherein the battery is rechargeable using wireless means (see col. 13, lines 51-57). The examiner considers that the battery is recharged wirelessly because an electromagnetic energy field does not require any wires.

6. Regarding Claims 5 and 6, Govari II discloses said physiological parameters include pressure (see col. 4, lines 8-12) and pressure gradient (see col. 4, lines 12-14 and col. 14, lines 29-36). The examiner considers that since pressure gradient is the

change in pressure over a given distance, then the variations in pressure along the length of the stent is the pressure gradient.

7. Regarding Claim 8, Govari II discloses a means for calculating change of pressure over time, dp/dt (see col. 14, lines 22-36).

8. Regarding Claim 9, Govari II discloses that the cardiac conduit is chosen from the group of artificial conduits (see col. 10, lines 18-21).

9. Regarding Claim 10, Govari II discloses at least one sensing device is located at one end of said cardiac conduit (see Figure 6). The examiner considers that the left-most sensor 84 is located at the left end of the cardiac conduit 24.

10. Regarding Claim 11, Govari II discloses at least one sensing device comprising a second sensing device at a second end of said cardiac conduit (see Figure 6). The examiner considers that the right-most sensor 84 is located at the right end of the cardiac conduit and is part of the left-most sensor 84 since they are connected.

11. Regarding Claim 12, Govari II discloses that the sensing device is adapted to indicate occlusion of said cardiac conduit (see col. 3, lines 14-18).

12. Regarding Claim 13, Govari II discloses at least one sensing device comprises a second sensing device (see left-most and right-most sensors 84) and said sensing devices are located on said cardiac conduit (axially along stent 24) so as to be operable for locating the occlusion (see col. 6, lines 24-28 and col. 14, lines 27-37).

13. Regarding Claim 14, Govari II discloses that the sensing devices are adapted for measuring flow rates through said cardiac conduit (see col. 10, lines 51-59).

14. Regarding Claim 15, Govari II does not disclose that the data from the sensing devices are useful to estimate time-to-failure within said cardiac conduit. Any implantable system with a sensor is *capable* of being used for estimation of time-to-failure [emphasis added].

15. Regarding Claim 16, Govari II discloses that the sensing device and the readout device are adapted for use for the assessment of stenosis (see col. 12, lines 49-67). The examiner considers that since the information from the sensing device are automatically sent to the readout device (see col. 11, lines 28-33), then the readout device is necessarily involved in the assessment of stenosis.

16. Regarding Claim 17, Govari II discloses a resonant scheme to couple said sensing device to the readout device (see col. 15, lines 4-13).

17. Regarding Claim 18, Govari II discloses one or more physiological parameters being pressure (see col. 4, lines 8-12).

18. Regarding Claim 19, Govari II discloses that the sensing device and said readout device are adapted for use for the early diagnosis of occlusion (see col. 3, lines 25-35) in said cardiac conduit.

19. Regarding Claim 20, Govari II discloses that the readout device (receiver 48) is capable of providing remote monitoring of said cardiac conduit (see Figure 3). The examiner considers that the wireless communication between the readout device and the stent allow for remote monitoring.

20. Regarding Claims 21 and 23-24, Govari II discloses that the sensing device comprises means for anchoring the sensing device to said cardiac conduit (see col. 14,

lines 56-67). The examiner considers that the stent wall and the sensor diaphragm work together to anchor the sensing device to the stent.

21. Regarding Claim 31, Govari II discloses that the anchoring means is made from a polymer (see silicon rubber; col. 14, lines 56-58).

22. Regarding Claim 32, Govari II discloses that the sensing device is augmented with one or more actuators including electrodes (see col. 17, lines 18-20).

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

24. Claims 7, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Govari et al. (US Patent 6,053,873), hereinafter Govari II, in view of Govari et al. (US Patent 6,636,769), hereinafter Govari I.

25. Regarding Claim 7, Govari II discloses a cardiac conduit (stent 24) adapted to be implanted in the patient so that after the cardiac conduit is implanted in the patient said at least one sensing device measures pressure in the artery (see col. 9, lines 64-66) or any other part of the body (see implantable cardiac assist pumps; col. 6, lines 57-62). However, Govari II does not explicitly disclose which artery or chamber the pressure is being measured in. Govari I discloses a similar sensor which measures pressure in the left or right atrium (see col. 10, lines 50-60). It would be obvious to one of ordinary skill

in the art at the time of the invention to specify which artery or cardiac chamber is sensed depending on what type of cardiac condition is being monitored (see CHF; col. 10, line 50).

26. Regarding Claims 29 and 30, Govari II does not disclose that the anchoring means is a helical screw. However, Govari I discloses the sensing device can have an anchoring means that is a helical screw (see Figure 3 and col. 3, lines 28-34) or a tine (see col. 6, lines 28-34). Nevertheless, it would have been an obvious matter of design choice to a person of ordinary skill in the art at the time of the invention to utilize the helical screw or tine of Govari I with the stent of Govari II because Applicant has not disclosed that the helical screw mechanism provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the stent wall as the anchoring mechanism because it provides attachment between the sensing devices and the stent and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Govari II.

27. Claims 33 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pawlak et al. (US Patent 5,135,538) in view of Govari et al. (US Patent 6,053,873), hereinafter Govari II.

28. Regarding Claims 33 and 37, Pawlak discloses a closed-loop medical treatment system that controls a valve dependent on pressure changes (see col. 8, line 64- col. 9, line 17) with the use of a pressure sensor (see col. 9, lines 2-6). Pawlak does not elaborate on the structure of the mechanism used to detect these changes. Govari II

discloses diagnosis (see col. 14, lines 27-36) by detecting changes with a pressure-sensing device (pressure sensors 84). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to treat a condition of the heart in a manner described by Pawlak using the pressure sensor disclosed by Govari because the sensing device is beneficial to providing the diagnosis necessary for determining the treatment. Finally, 'for control of said valve' is considered a statement of intended use and therefore does not patentably distinguish over the prior art.

29. Claims 34 and 35 rejected under 35 U.S.C. 103(a) as being unpatentable over Govari et al. (US Patent 6,053,873), hereinafter Govari II, in view of Weissman et al. (US Patent 6,092,530).

30. Regarding Claims 34 and 35, Govari II discloses that the sensing device is covered with a layer (see cap 95). However, Govari II does not disclose that the sensing device is coated with this layer. However, it is well-known and common to coat implanted devices to prevent thrombosis. Weissman is cited for coating a sensor with a polymer (see col. 6, line 65- col. 7, line 6). PTFE is a common polymer used in medical devices. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Govari's nonthrombogenic agent into Weissman's polymer to coat the sensor because it improves hemocompatibility and reduces thrombogenesis.

Allowable Subject Matter

31. Claims 36 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

33. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

35. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

36. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NNP
9/5/06

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